



## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1310

[Docket No. DEA-678]

### Designation of Methyl *alpha*-phenylacetoacetate, a Precursor Chemical Used in the Illicit Manufacture of Phenylacetone, Methamphetamine, and Amphetamine, as a List I Chemical

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration is proposing the control of the chemical methyl *alpha*-phenylacetoacetate (also known as MAPA; methyl 3-oxo-2-phenylbutanoate; methyl 2-phenylacetoacetate;  $\alpha$ -acetyl-benzeneacetic acid, methyl ester; and CAS Number: 16648-44-5) and its optical isomers as a list I chemical under the Controlled Substances Act (CSA). Methyl *alpha*-phenylacetoacetate is used in clandestine laboratories to illicitly manufacture the schedule II controlled substances phenylacetone (also known as phenyl-2-propanone or P2P), methamphetamine, and amphetamine and is important to the manufacture of these controlled substances. If finalized, this action would subject handlers of methyl *alpha*-phenylacetoacetate to the chemical regulatory provisions of the CSA and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of methyl *alpha*-phenylacetoacetate. As such, all transactions of chemical mixtures containing methyl *alpha*-phenylacetoacetate would be regulated at any concentration and would be subject to control under the CSA.

**DATES:** Comments must be submitted electronically or postmarked on or before

**[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL**

**REGISTER].** Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA-678” on all electronic and written correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration (DEA) encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment, in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3249.

**SUPPLEMENTARY INFORMATION:**

**Posting of Public Comments**

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this proposed rule is available at <http://www.regulations.gov> for easy reference.

## **Legal Authority**

The Controlled Substances Act (CSA) gives the Attorney General the authority to specify, by regulation, a chemical as a list I chemical. 21 U.S.C. 802(34). The term “list I chemical” means a chemical that is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of the controlled substance. *Id.* Pursuant to 28 CFR 0.100(b), the Attorney General has delegated his authority to designate list I chemicals to the Administrator of DEA (Administrator).

The DEA regulations set forth the process by which DEA may add a chemical as a listed chemical. As set forth in 21 CFR 1310.02(c), the agency may do so by publishing a final rule in the Federal Register following a published notice of proposed rulemaking with at least 30 days for public comments. The current list of all list I chemicals is available in 21 CFR 1310.02(a).

In addition, the United States is a party to the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988 Convention), December 20, 1988, 1582 U.N.T.S. 95. Under Article 12 of the 1988 Convention, when the United States receives notification that a chemical has been added to Table I or Table II of the 1988 Convention, the United States is required to take measures it deems appropriate to monitor the manufacture and distribution of that chemical within the United States and to prevent its diversion. The 1988 Convention also requires the United States to take other specified measures related to that chemical, including measures related to its international trade.

## **Background**

By letter dated May 7, 2020, in accordance with Article 12, paragraph 6 of the 1988 Convention, the Secretary-General of the United Nations informed the United States Government that the chemical methyl *alpha*-phenylacetoacetate (MAPA), including its optical isomers, was added to Table I of the 1988 Convention. This letter

was prompted by a March 4, 2020, decision at the 63<sup>rd</sup> Session of the United Nations Commission on Narcotic Drugs (CND) to add MAPA to Table I. As discussed above, the United States is a party to the 1988 Convention, and has certain obligations pursuant to Article 12. By designating MAPA as a list I chemical, the United States will fulfill its obligations under the 1988 Convention.

MAPA is used in, and is important to, the manufacture of the schedule II substances phenylacetone (also known as phenyl-2-propanone, P2P, or benzyl methyl ketone), methamphetamine, and amphetamine. Throughout the 1970s, methamphetamine was illicitly produced in the United States, primarily with the precursor chemical P2P. In response to the illicit use of P2P, DEA controlled P2P as a schedule II controlled substance in 1980 pursuant to the “immediate precursor” provisions of the CSA, specifically 21 U.S.C. 811(e).<sup>1</sup> Clandestine laboratory operators have circumvented this control by developing a variety of synthetic methods for producing P2P.

Congress and DEA responded by placing controls on precursor chemicals used in the illicit production of P2P, such as phenylacetic acid (and its salts and esters), acetic anhydride, benzyl cyanide, benzaldehyde, and nitroethane.<sup>2,3</sup> However, clandestine laboratory operators circumvented these controls by using alternative precursors that avoid the production of P2P: ephedrine and pseudoephedrine for the production of methamphetamine; and phenylpropanolamine for the production of amphetamine. This led Congress and DEA to place stringent controls on the manufacture, distribution, importation, and exportation of ephedrine (its salts, optical isomers, and salts of optical isomers), pseudoephedrine, and phenylpropanolamine (controlled as list I chemicals), and pharmaceutical products containing these chemicals through the Combat

---

<sup>1</sup> 44 FR 7182 (Feb. 11, 1980).

<sup>2</sup> On November 18, 1988, the Chemical Diversion and Trafficking Act (Subtitle A of Title VI of Pub. L. 100-690) was enacted.

<sup>3</sup> Under 21 CFR 1310.02(a), benzaldehyde, benzyl cyanide, nitroethane, and phenylacetic acid (including its salts and esters) are list I chemicals. Under 21 CFR 1310.02(b), acetic anhydride is a list II chemical.

Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Act Improvement and Reauthorization Act of 2005, Pub. L. 109-117), the Methamphetamine Production Prevention Act of 2008 (Pub. L. 110-415), and the Combat Methamphetamine Act of 2010 (Pub. L. 111-268).<sup>4</sup> The international community soon took similar measures.

With the growing problem of illicit drug production, the issue of precursor chemical control has gained global attention. International controls on precursors were first established under Article 12 of the 1988 Convention, which established two categories of controlled illicit drug precursor substances: Table I and Table II.<sup>5</sup> International efforts to prevent the illicit production of amphetamine-type stimulants (including amphetamine and methamphetamine), and international control of precursors, have since made significant progress. Two international entities have played a crucial role in this effort: the CND and the International Narcotics Control Board (INCB). The CND meets annually to consider and adopt a range of decisions and resolutions related to international drug control treaties, including the 1988 Convention. The INCB is an independent, quasi-judicial expert body for the implementation of the international drug control treaties, including the 1988 Convention.

In response to domestic and international controls on amphetamine and methamphetamine precursors, clandestine laboratory operators have continued to explore alternate methods of making these illicit drugs, including developing techniques to manufacture their own precursors and diverting other precursors to produce these precursors. The INCB reported the emergence of MAPA in late 2017, noting its use as a

---

<sup>4</sup> DEA implemented the Combat Methamphetamine Epidemic Act of 2005, the Methamphetamine Production Prevention Act of 2008, and the Combat Methamphetamine Enhancement Act of 2010 in a series of interim and final rules. 72 FR 17401 (Apr. 9, 2007), 72 FR 28601 (May 22, 2007), 73 FR 73549 (Dec. 3, 2008), 73 FR 79318 (Dec. 29, 2008), 75 FR 4973 (Feb. 1, 2010), 75 FR 10168 (Mar. 5, 2010), 75 FR 38915 (Jul. 7, 2010), 76 FR 20518 (Apr. 13, 2011), and 76 FR 74696 (Dec. 1, 2011).

<sup>5</sup> Table I and Table II are annexed to the Convention.

precursor for the production of P2P.<sup>6</sup> The emergence and increase in encounters of MAPA are linked to increased scrutiny over other P2P precursors, such as *alpha*-phenylacetoacetamide (APAA).<sup>7</sup> Although MAPA does not have any legitimate use and it has not been widely traded through legitimate channels, it is advertised by online suppliers.<sup>8</sup> Clandestine laboratory operators currently use MAPA to manufacture P2P, which they then convert to methamphetamine and amphetamine.

## MAPA

MAPA is known as methyl *alpha*-phenylacetoacetate; methyl 3-oxo-2-phenylbutanoate; methyl 2-phenylacetoacetate;  $\alpha$ -acetyl-benzeneacetic acid, methyl ester; and CAS Number: 16648-44-5. MAPA first emerged in late 2017 with the Netherlands reporting seizures totaling nearly 490 kg on Form D.<sup>9</sup> Belgium followed in 2018 with reports through the Precursors Incident Communication System (PICS) of more than 550 kg of MAPA seized.<sup>10</sup> China was reported as the alleged origin for all of the incidents in the Netherlands or Belgium where the origin was provided. The INCB reported an increase in the frequency of seizures and amounts seized reported through PICS since November 2018.<sup>11</sup>

MAPA is a close chemical relative of precursors controlled under the 1988 Convention (*e.g.*, APAAN and APAA) and the timing of its emergence suggests it is trafficked to circumvent these recent precursor controls. The INCB notes that MAPA does not have any legitimate use.<sup>12</sup> DEA has not identified any known legitimate use for

---

<sup>6</sup> Statement by Mr. Cornelis de Joncheere, President, International Narcotics Control Board, Reconvened sixty-second session of the Commission on Narcotic Drugs, 13 December 2019, at 1.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> Member countries use Form D to report to INCB annual information on substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances.

<sup>10</sup> The Precursors Incident Communication System or PICS is a worldwide, real-time, on-line tool for communication and information sharing between national authorities on precursor incidents to include seizures, stopped shipments, diversion and diversion attempts, illicit laboratories and associated equipment.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

MAPA, other than in small amounts for research, development, and laboratory analytical purposes. Due to the lack of industrial uses of MAPA, the chemical has not been widely available from legitimate chemical suppliers. Since late 2017, however, there have been large international seizures of MAPA, primarily in Europe, which suggest there is a ready supply of MAPA from international chemical manufacturers. The only use for a large quantity of MAPA of which DEA is aware is as a primary precursor for conversion to P2P, and subsequent conversion to amphetamine or methamphetamine.

Between late 2017, and May 7, 2019, the INCB noted 29 incidents from PICS where MAPA was seized. The amount of MAPA seized in individual incidents ranged from 500 grams to 2 metric tons, and totaled more than 10.5 metric tons. All incidents reported in PICS occurred in Europe, or involved shipments of MAPA destined for countries in Europe.

DEA has determined that MAPA is now readily available from commercial chemical suppliers and has identified seven potential suppliers in China, five potential suppliers in the United States, three potential suppliers in the United Kingdom, and one potential supplier each in France, Hong Kong, and Latvia.

DEA is concerned about the ease with which MAPA serves as a precursor chemical for illicit controlled substance production and with the international trafficking in this chemical. The international community shares this concern. The INCB found “that MAPA is frequently used in the illicit manufacture of amphetamine-type stimulants, namely amphetamine, and that the volume and extent of the illicit manufacture of amphetamine-type stimulants pose serious public health or social problems so as to warrant international action.”<sup>13</sup> Based in part on the findings of the INCB, and as noted

---

<sup>13</sup> Notification from the President of the INCB to the Chair of the CND on its sixty-third session concerning the scheduling of MAPA under the 1988 Convention, Nov. 12, 2019, at 1.



above, the CND has added MAPA to Table I of the 1988 Convention. Therefore, DEA is proposing the designation of MAPA as a list I chemical.

### **Proposed Designation of MAPA and its Optical Isomers as a List I Chemical**

For the reasons discussed above, the Acting Administrator of DEA finds that MAPA is used in the manufacture of controlled substances (*i.e.*, schedule II substances P2P, methamphetamine, and amphetamine) in violation of the CSA and is important to the manufacture of these controlled substances. Laboratory operators are using MAPA as the precursor material for the illicit manufacture of P2P, methamphetamine, and amphetamine. Therefore, the Acting Administrator proposes the designation of MAPA as a list I chemical.

If finalized, handlers of MAPA would become subject to the chemical regulatory provisions of the CSA, including 21 CFR parts 1309, 1310, 1313, and 1316. Since 1 gram of MAPA could make approximately 1 gram of methamphetamine hydrochloride, which is equivalent to approximately 200 tablets containing 5 milligrams of methamphetamine hydrochloride, this action does not propose the establishment of a threshold for domestic and import transactions of MAPA in accordance with the provisions of 21 CFR 1310.04(g). Therefore, DEA is proposing that all MAPA transactions, regardless of size, would be regulated transactions as defined in 21 CFR 1300.02(b). As such, if finalized, all MAPA transactions would be subject to recordkeeping, reporting, import and export controls, and other CSA chemical regulatory requirements. In addition, each regulated bulk manufacturer must submit manufacturing, inventory, and use data on an annual basis, in accordance with 21 CFR 1310.05(d).

### **Chemical Mixtures of MAPA**

This rulemaking also proposes that chemical mixtures containing MAPA would not be exempt from regulatory requirements at any concentration, unless a manufacturer submits to DEA an application for exemption of such chemical mixture, DEA accepts the

application for filing, and DEA exempts the chemical mixture in accordance with 21 CFR 1310.13 (Exemption of chemical mixtures by application). Since 1 gram of MAPA could make approximately 1 gram of methamphetamine hydrochloride, which is equivalent to approximately 200 tablets containing 5 milligrams of methamphetamine hydrochloride, regulation of chemical mixtures containing any amount of MAPA is necessary to prevent the illicit extraction, isolation, and use of MAPA. Therefore, all chemical mixtures containing any quantity of MAPA would be subject to control under the CSA, unless a manufacturer of MAPA is granted an exemption by the application process in accordance with 21 CFR 1310.13. This rulemaking proposes the modification of the “Table of Concentration Limits” in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of MAPA are subject to CSA chemical control provisions.

### **Application Process for Exemption of Chemical Mixtures**

DEA has implemented an application process to exempt certain chemical mixtures from the requirements of the CSA and its implementing regulations.<sup>14</sup> Manufacturers may submit an application for exemption for those mixtures that do not meet the criteria set forth in 21 CFR 1310.12(d) for an automatic exemption. Pursuant to 21 CFR 1310.13(a), DEA may grant an exemption of a chemical mixture, by publishing a final rule in the Federal Register, if DEA determines that: 1) the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance, and 2) the listed chemical or chemicals cannot be readily recovered.

### **Requirements for Handling List I Chemicals**

If finalized as proposed, the designation of MAPA as a list I chemical would subject handlers (manufacturers, distributors, importers, and exporters) and proposed handlers to all of the regulatory controls and administrative, civil, and criminal sanctions

---

<sup>14</sup> 21 CFR 1310.13 specifies that this chemical mixture is a chemical mixture consisting of two or more chemical components, at least one of which is a list I or list II chemical.

applicable to the manufacture, distribution, importing, and exporting of a list I chemical. Upon publication of a final rule, persons potentially handling MAPA, including regulated chemical mixtures containing MAPA, would be required to comply with the following list I chemical regulations:

1. *Registration.* Any person who handles (manufactures, distributes, imports, or exports), or proposes to engage in such handling of, MAPA or a chemical mixture containing MAPA must obtain a registration pursuant to 21 U.S.C. 822, 823, 957, and 958. Regulations describing registration for list I chemical handlers are set forth in 21 CFR part 1309. DEA regulations require separate registrations for manufacturing, distributing, importing, and exporting of MAPA.<sup>15</sup> Further, a separate registration is required for each principal place of business at one general physical location where list I chemicals are manufactured, distributed, imported, or exported by a person.<sup>16</sup>

DEA notes that under the CSA, “warehousemen” are not required to register and may lawfully possess list I chemicals, if the possession of those chemicals is in the usual course of business or employment.<sup>17</sup> Under DEA implementing regulations, the warehouse in question must receive the list I chemical from a DEA registrant and shall only distribute the list I chemical back to the DEA registrant and registered location from which it was received.<sup>18</sup> A warehouse that distributes list I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register as such.

Upon publication of a final rule, any person manufacturing, distributing, importing, or exporting MAPA or a chemical mixture containing MAPA would become subject to the registration requirement under the CSA. DEA recognizes, however, that it

---

<sup>15</sup> 21 CFR 1309.21.

<sup>16</sup> 21 CFR 1309.23(a). See also 21 U.S.C. 822(e)(1) with separate registration requirements pertaining to manufacturing or distributing a list I chemical.

<sup>17</sup> 21 U.S.C. 822(c)(2) and 21 U.S.C. 957(b)(1)(B).

<sup>18</sup> See 21 CFR 1309.23(b)(1).

is not possible for persons who are subject to the registration requirements to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, to allow any continued legitimate commerce in MAPA, DEA is proposing to establish in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with MAPA, provided that DEA receives a properly completed application for registration on or before 30 days after publication of a final rule implementing regulations regarding MAPA. The temporary exemption for such persons would remain in effect until DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption would apply solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, would become effective on the effective date of the final rule. Therefore, all transactions of MAPA and chemical mixtures containing MAPA would be regulated while an application for registration or exemption is pending. This is necessary because a delay in regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption for registration does not suspend applicable Federal criminal laws relating to MAPA, nor does it supersede State or local laws or regulations. All handlers of MAPA must comply with applicable State and local requirements in addition to the CSA regulatory controls.

2. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports to DEA with respect to MAPA pursuant to 21 U.S.C. 830(a) and (b)(1) and (2) and in accordance with 21 CFR 1310.04 and 1310.05. Pursuant to 21 CFR 1310.04, a record must be made and maintained for two

years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical would be required to submit manufacturing, inventory, and use data on an annual basis.<sup>19</sup> Existing standard industry reports containing the required information would be acceptable, provided the information is separate or readily retrievable from the report.

The CSA and its implementing regulations require that each regulated person must report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of subchapter I of the CSA. In addition, regulated persons must report any proposed regulated transaction with a person whose description or other identifying characteristics DEA has previously furnished to the regulated person, any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier.<sup>20</sup>

3. *Importation and Exportation.* All importation and exportation of MAPA would need to be in compliance with 21 U.S.C. 957, 958, and 971 and in accordance with 21 CFR part 1313.

4. *Security.* All applicants and registrants would be required to provide effective controls against theft and diversion of list I chemicals in accordance with 21 CFR 1309.71-1309.73.

5. *Administrative Inspection.* Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, or otherwise dispose of a list I chemical or where

---

<sup>19</sup> 21 CFR 1310.05(d).

<sup>20</sup> 21 USC 830(b) and 21 CFR 1310.05(a) and (b).

records relating to those activities are maintained, are controlled premises as defined in 21 U.S.C. 880(a) and 21 CFR 1316.02(c). The CSA allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316, subpart A.<sup>21</sup>

6. *Liability.* Any activity involving MAPA not authorized by, or in violation of, the CSA would be unlawful, and would subject the person to administrative, civil, and/or criminal action.

## **REGULATORY ANALYSES**

*Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)*

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB) as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients

---

<sup>21</sup> 21 U.S.C. 880.

thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. DEA has determined that this proposed rule is not a "significant regulatory action" under E.O. 12866, section 3(f).

If finalized as proposed, MAPA would be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of list I chemicals. MAPA is used in, and is important to, the illicit manufacture of the schedule II-controlled substances P2P, methamphetamine, and amphetamine.

DEA has searched information in the public domain for any legitimate uses of this chemical. Other than the small amounts for research, development, and laboratory analytical purposes, DEA has not documented any industrial use for MAPA except for it being a chemical intermediate in the production of the schedule II substances P2P, methamphetamine, and amphetamine. Based on the review of established aggregate production quota for P2P (40 grams for 2019), legal conversion of MAPA to P2P in the United States, if it takes place at all, is limited to small, gram quantities. Therefore, DEA concludes the vast majority of, if not all, MAPA is used for the manufacturing of illicit P2P, methamphetamine, and amphetamine.

DEA cannot rule out the possibility that minimal quantities of MAPA are used for the manufacturing of legitimate P2P. However, if there are any quantities of MAPA used for the manufacturing of legitimate P2P, the quantities are believed to be minimal. DEA welcomes any public comment on these quantities and their economic significance.

DEA evaluated the costs and benefits of this proposed action.

#### Costs

DEA believes the market for MAPA for the legitimate manufacturing of pharmaceutical amphetamine or methamphetamine is minimal. As stated above, the only use for MAPA of which DEA is aware is as a chemical intermediate for the manufacture

of P2P, methamphetamine, and amphetamine. Any manufacturer, distributor, importer, or exporter of MAPA for the production of legitimate P2P, methamphetamine, and amphetamine, if they exist at all, would incur costs if this proposed rule were finalized. The primary costs associated with this proposed rule would be the annual registration fees for manufacturers (\$3,699) and for distributors, importers, and exporters (\$1,850). However, any manufacturer that uses MAPA for legitimate P2P, methamphetamine, and amphetamine production would already be registered with DEA and have all security and other handling processes established because of the controls already in place on P2P, methamphetamine, and amphetamine, resulting in minimal cost to those entities. As there are different forms of handling the scheduled substances versus the list I chemical (distribution of P2P, methamphetamine, and amphetamine versus exporting MAPA), this could require a separate registration for the different handling of the substances. If an entity is already registered to handle, manufacture, import, or export a scheduled substance, the entity would not need an additional registration for the list I chemical, provided it is handling the list I chemical in the same manner that it is registered for with the scheduled substance, or as a coincident activity permitted by § 1309.21. Even with the possibility of these additional registrations, DEA believes that the cost would be minimal.

DEA has identified five domestic suppliers of MAPA, only one of which is registered with DEA to handle list I chemicals. It is difficult to estimate the quantity of MAPA these suppliers distribute. Chemical distributors often have items in their catalog while not actually having any material level of sales. If this proposed rule is finalized, suppliers for the legitimate use of MAPA, if any, are expected to choose the least-cost option, and stop selling the minimal quantities of MAPA, rather than incur the registration cost. Because DEA believes the quantities of MAPA supplied for the legitimate manufacturing of P2P, methamphetamine, and amphetamine are minimal,



DEA estimates that the cost of foregone sales is minimal; and thus, the cost of this proposed rule is minimal. DEA welcomes any public comment regarding this estimate.

This analysis excludes consideration of any economic impact to those businesses that facilitate the manufacture and distribution of MAPA for the production of manufacturing illicit P2P, methamphetamine, and amphetamine. As a law enforcement organization and as a matter of principle, DEA believes considering the economic utility of facilitating the manufacture of illicit P2P, methamphetamine, and amphetamine would be improper.

### Benefits

Controlling MAPA is expected to prevent, curtail, and limit the unlawful manufacture and distribution of the controlled substances P2P, methamphetamine, and amphetamine. As a list I chemical, handling of MAPA would require registration with DEA, various controls, and monitoring as required by the CSA. This proposed rule is also expected to assist in preventing the possible theft or diversion of MAPA from any legitimate firms. DEA also believes control is necessary to prevent unscrupulous chemists from synthesizing MAPA and selling it (as an unregulated material) through the Internet and other channels, to individuals who may wish to acquire an unregulated chemical intermediate for the purpose of manufacturing illicit P2P, methamphetamine, and amphetamine.

In summary, DEA conducted a qualitative analysis of costs and benefits. DEA believes this proposed action, if finalized, will minimize the diversion of MAPA. DEA believes the market for MAPA for the legitimate manufacturing of P2P, methamphetamine, and amphetamine is minimal. Therefore, any potential cost as a result of this regulation is minimal.

*Executive Order 12988, Civil Justice Reform*

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

*Executive Order 13132, Federalism*

This proposed rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

*Executive Order 13175, Consultation and Coordination with Indian Tribal Governments*

This proposed rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

*Regulatory Flexibility Act*

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA),<sup>22</sup> has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. As discussed above, if finalized as proposed, MAPA would be subject to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, and exportation of list I chemicals. MAPA is used in, and is important to, the illicit manufacture of the schedule II-controlled substances P2P, methamphetamine, and amphetamine. DEA has not identified any legitimate industrial use for MAPA, other than its role as a chemical intermediate in the production of P2P,

---

<sup>22</sup> 5 U.S.C. 601-612.

methamphetamine, and amphetamine. Based on the review of established aggregate production quota for P2P, 40 grams for 2019, legal conversion of MAPA to P2P in the United States, if it takes place at all, is limited to small, gram quantities. Therefore, DEA believes the vast majority, if not all, of MAPA is used for the illicit manufacturing of P2P, methamphetamine, and amphetamine. The primary costs associated with this proposed rule are the annual registration fees (\$3,699 for manufacturers and \$1,850 for distributors, importers, and exporters). Additionally, any manufacturer that uses MAPA for legitimate P2P, methamphetamine, and amphetamine production would already be registered with DEA and have all security and other handling processes in place, resulting in minimal cost.

DEA has identified five domestic suppliers of MAPA, only one of which is registered with DEA to handle list I chemicals. Based on Small Business Administration (SBA) size standards for chemical distributors and Statistics of U.S. Business data, each of the five suppliers are small entities because their revenues are below SBA's \$150 million threshold. It is difficult to estimate the quantity of MAPA these suppliers distribute. Chemical distributors often have items in their catalog while not actually having any material level of sales. Based on the review of established aggregate production quota for P2P (40 grams for 2019), legal conversion of MAPA to P2P in the United States is limited to small, gram quantities. DEA believes any quantity of sales of MAPA from these distributors for legitimate P2P manufacturing is minimal. Therefore, DEA estimates the cost of this proposed rule on any affected small entity is minimal. DEA welcomes any public comment regarding this estimate. Based on these factors, DEA projects that this proposed rule, if promulgated, will not result in a significant economic impact on a substantial number of small entities.

*Unfunded Mandates Reform Act of 1995*

On the basis of information contained in the RFA section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year \* \* \*.” Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

*Paperwork Reduction Act*

This proposed action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501-3521. This proposed action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

**List of Subjects in 21 CFR Part 1310**

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, DEA proposes to further amend 21 CFR part 1310, as proposed to be amended at 85 FR 82984 (December 21, 2020) as follows:

**PART 1310— RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES**

1. The authority citation for 21 CFR part 1310 continues to read as follows:

**Authority:** 21 U.S.C. 802, 827(h), 830, 871(b), 890.

2. In § 1310.02, add paragraph (a)(37) to read as follows:

**§ 1310.02 Substances covered.**

\* \* \* \* \*

(a) \* \* \*

(37) methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate)  
and its optical isomers.....8795

\* \* \* \* \*

3. In § 1310.04:

- a. Redesignate paragraphs (g)(1)(x) through (xvi) as paragraphs (g)(1)(xi) through (xvii), respectively; and
- b. Add new paragraph (g)(1)(x).

The addition reads as follows:

**§ 1310.04 Maintenance of records.**

\* \* \* \* \*

(g) \* \* \*

(1) \* \* \*

(x) methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate)  
and its optical isomers

\* \* \* \* \*

4. In § 1310.09, add paragraph (r) to read as follows:

**§ 1310.09 Temporary exemption from registration.**

\* \* \* \* \*

(r)(1) Each person required under 21 U.S.C. 822 and 957 to obtain a registration to manufacture, distribute, import, or export regulated forms of methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers,

including regulated chemical mixtures pursuant to § 1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing regulated forms of MAPA pursuant to § 1310.13 on or before 30 days after the publication of a rule finalizing this action. The exemption would remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing regulated forms of methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement would also be provided for those persons whose application for exemption is denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons would remain in effect until DEA takes final action on their registration application.

5. In § 1310.12, in the Table of Concentration Limits under List I Chemicals in paragraph (c), add an entry for methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) in alphabetical order to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

\* \* \* \* \*

(c) \* \* \*

TABLE OF CONCENTRATION LIMITS

DEA chemical code number	Concentration	Special conditions
List I Chemicals		
* * * * *		
methyl <i>alpha</i> - phenylacetoacetate (MAPA; methyl 3-oxo- 2-phenylbutanoate) and its optical isomers .....	8795	Not exempt at any concentration Chemical mixtures containing any amount of MAPA and its optical isomers are not exempt
* * * * *		

\* \* \* \* \*

**D. Christopher Evans,**

*Acting Administrator.*